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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/647,919 | 08/26/2003 | Paul Joseph Dominowski | 15634 (PC25246) | 2440 |

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| EXAMINER | |
|---|---|
| HURT, SHARON L | |
| **ART UNIT** | **PAPER NUMBER** |
| 1648 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/647,919 | DOMINOWSKI, PAUL JOSEPH | |
| | Examiner | Art Unit | |
| | Sharon Hurt | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 March 2007 and 28 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5,7-23,25,27-77 and 79-82* is/are pending in the application.

4a) Of the above claim(s) *12-19 and 32-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-11,20-23,25,27-31,76,77 and 79-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 28, 2007 has been entered.

### *Response to Amendment*

The amendments to the claims filed March 21, 2007 and June 28, 2007 have been entered. Claims 1-12, 18, 20-21, 23-31, 54, 70-72 and 77-83 are currently amended in the amendment filed March 21, 2007.

### *Status of the Claims*

Claims 1-5, 7-23, 25, 27-77 and 79-82 are pending. Claims 6, 24, 26, 78 and 83 have been canceled. Claims 12-19 and 32-75 are withdrawn from consideration. Claims 1-5, 7-11, 20-23, 25, 27-31, 76-77 and 79-82 are under examination.

### *Response to Arguments*

### *Claim Rejections - 35 USC § 102*

The rejection of claims 1-2, 7-11, 20-21, 27-31, 79, and 80-82 under 35 U.S.C. 102(b) as being anticipated by Bowland et al. **is withdrawn**. Applicant's arguments, see page 12, filed

March 21, 2007, with respect to modified live virus as opposed to inactivated virus have been fully considered and are persuasive.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1-11, 20-31 and 76-83 under 35 U.S.C. 103(a) as being unpatentable over Talens et al. **or** Bowland et al. in view of Barr et al., Pruette et al. and Wilson et al. **is maintained for claims 1-5, 7-11, 20-23, 25, 27-31, 76-77 and 79-82.**

Applicant's arguments filed March 21, 2007 and June 28, 2007 have been fully considered but they are not persuasive. Applicant argues that both Talen and Bowland references contain only one strain of BVDV antigen. The package insert for BOVI-SHIELD™ 3 indicates the vaccine comprises BVD (Type 1 and Type 2) virus. Applicant also argues that "neither Barr, Pruett, nor Wilson teach nor suggest the adjuvant compositions of the present invention". Applicant argues that Barr neither teaches nor suggests combining Quil A with an oil-in-water emulsion such as Amphigen. Applicant also argues that Pruett has no teaching for combining Quil A and Amphigen. Applicant argues that Pruett suggests the mixture of Alhydrogel and Amphigen formulation for use only with hypodermin A. Applicant further argues that Wilson does not suggest combining Amphigen and Quil A.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As set forth *In re Kerkoven*, 205 USPQ 1069 (CCPA 1980), It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose...the idea of combining them flows logically from their having been individually taught in prior art.

Applicant argues that BOVI-SHIELD™ 3 only contains IBRV, PI3 and BVDV and the present invention includes BHV-1, PI-3, BRSV, BVDV-1 and BVDV-2. Bowland teaches that BOVI-SHIELD™ 4 (see page 36, Table 1) includes IBRV (BHV-1), PI-3V, BRSV and BVDV. Therefore Bowland teaches all 4 viruses including BVDV Types 1 and 2. Applicant also argues that BOVI-SHIELD™ 3 is a modified live vaccine composition while the instant invention comprises two inactivated strains of BVD viral antigens. It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use inactivated virus for the multivalent vaccine composition. Attenuated virus and killed virus are considered functionally equivalent therefore it would have been obvious to substitute one for the other. The person of ordinary skill in the art would have been motivated to make that (those) modification(s) because Bowland also teaches killed virus vaccines for BVDV such as Cattlemaster™ BVD-K (see page 37, Table 1), and reasonably would have expected success because of the success of the commercial vaccines taught by Bowland.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7-11, 20-23, 25, 27-31, 76-77 and 79-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowland et al. in view of Brake et al. (US Patent No. 6,787,146, Sep. 2004).

The claimed invention is drawn to an immunogenic and a vaccine composition comprising a modified live Bovine Herpesvirus Virus (BHV-1), a modified live Parainfluenza Virus Type 3 (PI-3), a modified live Bovine Respiratory Snycytial Virus (BRSV), an adjuvant, Bovine Viral Diarrhea Virus Type-1 (BVDV-1), a Bovine Viral Diarrhea Virus Type-2 (BVDV-2) and a veterinary-acceptable carrier, wherein BVDV-1 and BVDV-2 are inactivated, wherein said adjuvant comprises a saponin, a saponin-containing oil-in-water emulsion, Quil A, lecithin and oil blend, and cholesterol, wherein said adjuvant is microfluidized, wherein the immunogenic and vaccine composition further comprises a *Leptospira* or *Campylobacter fetus* antigen, wherein BVDV-1 and BVDV-2 is cytopathic or noncytopathic.

Boland et al. discloses current commercial vaccines available in Canada for bovine respiratory disease. Vaccines include infectious bovine rhinotrachetitis virus [(IBRV), bovine herpesvirus-1, (BHV-1)], bovine viral diarrhea virus (BVDV), bovine respiratory syncytial virus (BRSV), parainfluenza-3 virus (PI-3), and bacterial antigens including *Leptospira* serovars (page 33 and Table 1 pages 43-45). Some of the multi-vaccines included adjuvants (Table 1, pages 43-

45). Bowland teaches the vaccine compositions and intended use of the multi-vaccines. Bowland et al. do not teach a vaccine composition with an adjuvant comprising Quil A, Amphigen (lecithin and oil blend) and cholesterol.

Brake et al (hereinafter Brake) discloses a vaccine for cattle against bovine Neospora comprising a veterinary acceptable adjuvant comprising SEAM62 (column 8, lines 36-50). SEAM62 is an oil-in-water emulsion containing Quil A, lecithin and cholesterol (column 12, lines 59-67).

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use an oil-in-water emulsion adjuvant for the immunogenic or vaccine composition. The person of ordinary skill in the art would have been motivated to use an oil-in-water emulsion adjuvant because Brake teaches the preparation is a veterinary acceptable adjuvant, and reasonably would have expected success because of the *in vitro* immunization and challenge in mice experiments described by Brake.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Miller et al. (American Journal of Veterinary Research, April 1989, Vol. 50, No. 4, pages 551-554) teaches bovine herpesvirus-1 (BNV-1) is the pathogen of infectious bovine rhinotracheitis (IBR) (page 551, 1st paragraph).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

July 20, 2007

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